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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Lesley MURRAY et al.
Title: TREATMENT OF EXCESSIVE OSTEOLYSIS WITH INDOLINONE COMPOUNDS
Appl. No.: 10/780,917
Filing Date: 02/19/2004
Examiner: Unassigned
Art Unit: Unassigned

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document, except as noted below, is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

Applicants respectfully request that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.


The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date

19 May 2004

By



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Attorney for Applicant
Registration No. 35,087

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Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	10/780,917
		Filing Date	02/19/2004
		First Named Inventor	Lesley Murray
		Group Art Unit	Unassigned
		Examiner Name	Unassigned
		Attorney Docket Number	034536-1035
Sheet	1	of	4

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	6,573,293	B2	TANG et al.	06-03-2003	
	A2	6,642,232	B2	MATTSON et al.	11-04-2003	
	A3	6,653,308	B2	GUAN et al.	11-25-2003	
	A4	2004/0018528	A1	MORIMOTO et al.	01-29-2004	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	A5	WO	00/08202	A2	SUGEN, INC.	02-17-2000		
	A6	WO	01/60814	A2	SUGEN, INC.	08-23-2001		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A7	BRANDI et al., "Bidirectional regulation of osteoclast function by nitric oxide synthase isoforms," <u>Proc. Natl. Acad. Sci. USA</u> , March 1995, pp. 2954-2958, Vol. 92	
	A8	CLOHISY et al., "Review of Cellular Mechanisms of Tumor Osteolysis," <u>Clinical Orthopaedics and Related Research</u> , 2000, pp. 104-114, No. 373, Lippincott Williams & Wilkins, Inc.	
	A9	COLEMAN et al., "Osteoclast inhibition for the treatment of bone metastases," <u>Cancer Treatment Reviews</u> , January 1993, pp. 79-103, Vol. 19, No. 1, Academic Press Limited	

Examiner Signature	Date Considered
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	A10	DAVIES et al., "The Osteoclast Functional Antigen, Implicated in the Regulation of Bone Resorption, Is Biochemically Related to the Vitronectin Receptor," <u>The Journal of Cell Biology</u> , October 1989, pp. 1817-1826, Vol. 109, No. 4, Part 1, The Rockefeller University Press			
	A11	DEMERS et al., "Biochemical Markers and Skeletal Metastases," <u>Cancer Supplement</u> , June 15, 2000, pp. 2919-2926, Vol. 88, No. 12, John Wiley & Sons, Inc.			
	A12	FISHER et al., "Inhibition of Osteoclastic Bone Resorption in Vivo by Echistatin, an "Arginyl-Glycyl-Aspartyl" (RGD)-Containing Protein," <u>Endocrinology</u> , 1993, pp. 1411-1413, Vol. 132, No. 3, The Endocrine Society, USA			
	A13	FLICK et al., "Recognition of activated CSF-1 receptor in breast carcinomas by a tyrosine 723 phosphospecific antibody," <u>Oncogene</u> , May 29, 1997, pp. 2553-2561, Vol. 14, No. 21, Stockton Press			
	A14	FRIEDMAN et al., "Thyrocalcitonin: Inhibitor of Bone Resorption in Tissue Culture," <u>Science</u> , December 10, 1965, pp. 1465-1467, Vol. 150			
	A15	HALL et al., "Taxol Inhibits Osteoclastic Bone Resorption," <u>Calcified Tissue International</u> , December 1995, pp. 463-465, Vol. 57, No. 6, Springer-Verlag New York Inc.			
	A16	HENTUNEN et al., "Inhibition of Bone Resorption by a Monoclonal Antibody That Reacts with a 150 kD Membrane Protein in Chicken Osteoclasts," <u>Journal of Bone and Mineral Research</u> , October 1991, pp. 1091-1097, Vol. 6, No. 10, Mary Ann Liebert, Inc. Publishers			
	A17	HUNT et al., "Cellular mechanisms of bone resorption in breast carcinoma," <u>British Journal of Cancer</u> , 2001, pp. 78-84, Vol. 85, No. 1, Cancer Research Campaign			
	A18	JILKA et al., "Increased Osteoclast Development After Estrogen Loss: Mediation by Interleukin-6," <u>Science</u> , July 3, 1992, pp. 88-91, Vol. 257			
	A19	KACINSKI et al., "FMS (CSF-1 receptor) and CSF-1 transcripts and protein are expressed by human breast carcinomas <i>in vivo</i> and <i>in vitro</i> ," <u>Oncogene</u> , June 1991, pp. 941-952, Vol. 6, No. 6, Macmillan Press Ltd.			
	A20	KACINSKI, "CSF-1 and Its Receptor in Ovarian, Endometrial and Breast Cancer," <u>Annals of Medicine</u> , February 1995, pp. 79-85, Vol. 27, No. 1			
	A21	KACINSKI, "CSF-1 and Its Receptor in Breast Carcinomas and Neoplasms of the Female Reproductive Tract," <u>Molecular Reproduction and Development</u> , January 1997, pp. 71-74, Vol. 46, No. 1, Wiley-Liss			

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		Application Number Filing Date First Named Inventor Group Art Unit Examiner Name Attorney Docket Number	10/780,917 02/19/2004 Lesley Murray Unassigned Unassigned 034536-1035
Sheet	3	of	4

NON PATENT LITERATURE DOCUMENTS			
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	A22	MAHER et al., "Prognostic Significance of Colony-stimulating Factor Receptor Expression in Ipsilateral Breast Cancer Recurrence," <u>Clinical Cancer Research</u> , August 1998, pp. 1851-1856, Vol. 4, No. 8, American Association of Cancer Research	
	A23	MANCINO et al., "Breast Cancer Increases Osteoclastogenesis by Secreting M-CSF and Upregulating RANKL in Stromal Cells," <u>Journal of Surgical Research</u> , September 2001, pp. 18-24, Vol. 100, No. 1, Academic Press	
	A24	MUNDY, "Regulation of Bone Formation by Bone Morphogenetic Proteins and Other Growth Factors," <u>Clinical Orthopaedics and Related Research</u> , 1996, pp. 24-28, No. 323, Lippincott-Raven Publishers	
	A25	MUNDY, "Cytokines and Growth Factors in the Regulation of Bone Remodeling," <u>Journal of Bone and Mineral Research</u> , December 1993, pp. S505-S510, Vol. 8, Supplement 2, Mary Ann Liebert, Inc., Publishers	
	A26	O'NEILL et al., "Effect of Retinoic Acid on the Resorptive Activity of Chick Osteoclasts <i>in Vitro</i> ," <u>Bone</u> , 1992, pp. 23-27, Vol. 13, No. 1, Pergamon Press plc, USA	
	A27	PEDERSON et al., "Identification of Breast Cancer Cell Line-derived Paracrine Factors That Stimulate Osteoclast Activity," <u>Cancer Research</u> , November 15, 1999, pp. 5849-5855, Vol. 59	
	A28	QUINN et al., "Human Tumour-Associated Macrophages Differentiate Into Osteoclastic Bone-Resorbing Cells," <u>Journal of Pathology</u> , January 1998, pp. 31-36, Vol. 184, No. 1, John Wiley & Sons, Ltd.	
	A29	ROBINS et al., "Standardization of pyridinium crosslinks, pyridinoline and deoxypyridinoline, for use as biochemical markers of collagen degradation," <u>Clinical Chemistry</u> , 1996, pp. 1621-1626, Vol. 42, No. 10	
	A30	SCHMIDT et al., "Characterization of spontaneous metastasis in an aggressive breast carcinoma model using flow cytometry," <u>Clinical & Experimental Metastasis</u> , 1999, pp. 537-544, Vol. 17, No. 6, Kluwer Academic Publishers, Netherlands	
	A31	TAKAHASHI et al., "Downregulation of Calcitonin Receptor mRNA Expression by Calcitonin during Human Osteoclast-like Cell Differentiation," <u>J. Clin. Invest.</u> , January 1995, pp. 167-171, Vol. 95, No. 1, The Rockefeller University Press	
	A32	TAMURA et al., "The Relationship between Urinary Pyridinoline, Deoxypyridinoline and Bone Metastasis in a Rat Breast Cancer Model," <u>Breast Cancer</u> , January 1999, pp. 23-28, Vol. 6, No. 1	
	A33	TANAKA et al., "Macrophage Colony-stimulating Factor is Indispensable for both Proliferation and Differentiation of Osteoclast Progenitors," <u>J. Clin. Invest.</u> , January 1993, pp. 257-263, Vol 91, No. 1, The Rockefeller University Press	

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	A34	TANG et al., "M-CSF (Monocyte Colony Stimulating Factor) and M-CSF Receptor Expression by Breast Tumour Cells: M-CSF Mediated Recruitment of Tumour Infiltrating Monocytes?" <u>Journal of Cellular Biochemistry</u> , December 1992, pp. 350-356, Vol. 50, No. 4, Wiley-Liss, Inc.	
	A35	TOY et al., "The Activated Macrophage Colony-Stimulating Factor (CSF-1) Receptor as a Predictor of Poor Outcome in Advanced Epithelial Ovarian Carcinoma," <u>Gynecologic Oncology</u> , 2001, pp. 194-200, Vol. 80, Academic Press	
	A36	WEBBER et al., "Correlation of an Osteoclast Antigen and Ruffled Border on Giant Cells Formed in Response to Resorbable Substrates," <u>Journal of Bone and Mineral Research</u> , 1990, pp. 401-410, Vol. 5, No. 4, Mary Ann Liebert, Inc., Publishers	
	A37	YASUDA et al., "Osteoclast differentiation factor is a ligand for osteoprotegerin/osteoclastogenesis-inhibitory factor and is identical to TRANCE/RANKL," <u>Proc. Natl. Acad. Sci. USA</u> , March 1998, pp. 3597-3602, Vol. 95, The National Academy of Sciences	
	A38	YEE et al., "The Constitutive Production of Colony Stimulating Factor 1 by Invasive Human Breast Cancer Cells," <u>Anticancer Research</u> , November-December 2000, pp. 4379-4384, Vol. 20, No. 6B	
	A39	YONEDA et al., "Suramin Suppresses Hypercalcemia and Osteoclastic Bone Resorption in Nude Mice Bearing a Human Squamous Cancer," <u>Cancer Research</u> , May 1, 1995, pp. 1989-1993, Vol. 55, No. 9	

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